REMARKS/ARGUMENTS

This case has been carefully reviewed and analyzed in view of the Official Action dated 1 November 2005. Responsive to the objections and rejections made in the Official Action, Claims 1, 15, 19, 21-27, 30, 31 and 33-40 have been amended to clarify the language thereof and/or the combination of elements which form the invention of the subject Patent Application. Additionally, Claims 10-14, 20 and 122-128 have been canceled by this Amendment and Claims 41-121 are withdrawn.

The Specification has been amended to correct a typographical error found therein.

In the Official Action, the Examiner objected to Claims 30 and 39 due to informalities and rejected Claims 30 and 39 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. In particular, the Examiner stated that the Claims included the limitation of "constant level of perceptability to the patient", which was indefinite because it was dependent upon the patient and other outside factors such as the environment. Accordingly, Claims 30 and 39 have been amended to correct the language thereof. Rather than describing the alarm signal in terms of the patient, whose perception is varied and a function of many outside factors, the alarm signal has been described in terms of what it is, a sensory stimuli. Therefore, Claims 30 and 39 now call for a constant

level of sensory stimulation, which is independent of the patient or the environment in which the patient is located. As perception is a detection or awareness of a physical sensation, it is the result of a sensory stimulation, provided by the patient alarm means of the invention of the subject Patent Application. Thus, it is now believed that the Claims particularly point out and distinctly claim the subject matter that Applicants regard as the invention.

In the Official Action, the Examiner indicated that Claims 22 and 27 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Accordingly, Claim 22 has been amended to incorporate the subject matter of Claims 1 and 21 therein. Therefore, Claim 22 has been rewritten in independent form to include all of the limitations of the base claim, Claim 1, and the only intervening claim, Claim 21. Claim 27 has been amended to incorporate the subject matter of Claims 1 and 25 therein, thereby placing Claim 27 in independent form to include all of the limitations of the base claim, Claim 1, and the only intervening claim, Claim 25. Therefore, Claims 22 and 27 should now be allowable.

In the Official Action, the Examiner rejected Claims 1-7, 25 and 28 under 35 U.S.C. § 102(a), as being anticipated by Ujhelyi, et al., U.S. Published Patent Application 2003/0050566. In particular, the Examiner noted that the reference "mentioned tiered alerts" and therefore equated such to being equivalent to Applicant's escalating alarm signals.

Before discussing the prior art relied upon by the Examiner, it is believed beneficial to first briefly review the structure of the invention of the subject Patent Application, as now defined in Claim 1. The invention of the subject Patent Application is directed to a system for detection of cardiac events occurring in a human patient. The system includes at least two electrodes for obtaining an electrical signal from a patient's heart and an electrical signal processor electrically coupled to the electrodes for processing the electrical signal. The system further includes patient alarm means coupled to the electrical signal processor for generating a sensory alarm signal received by the patient over a predetermined time period subsequent to the electrical signal processor detecting a cardiac event. The alarm signal includes a multiplicity of successive sets of alerting signals, each set including two or more alerting signals. The alerting signals within each set are spaced apart in time by an intra-set time interval. The alarm signal escalates in sensory stimulation by decreasing the intra-set time interval in successive sets of alerting signals during the predetermined time period.

In contradistinction, the Ujhelyi, et al. reference is directed to an arrhythmia notification system incorporated in an implantable medical device. The implantable device 50 includes a notification module 50 that may be programmed to issue tiered alerts, "which includes an arrhythmia state relating to a combination of onset, post pacing, and burden criteria." Thus, the "tiered alerts" relates to the criteria for issuing the alert, and not the alerting signal which is output by the

system, as the Examiner contends. That interpretation is further confirmed by examination of the Claims. The Examiner is respectfully referred to Claim 8, wherein it includes the limitation of "... a trigger criterion selected from the group consisting of ... a tiered alert status ...".

Nowhere does the reference disclose or suggest any output of an alarm that provides escalating sensory stimulation in order to ensure that the alarm will be perceived by the patient and/or the medical practitioner. Therefore, as the reference fails to disclose each and every one of the elements of the invention of the subject Patent Application, it cannot anticipate that invention. Further, as the reference fails to suggest such a combination of elements, and in fact fails to recognize the problem solved by the invention of the subject Patent Application, it cannot make obvious that invention either.

In the Official Action, the Examiner rejected Claims 1-4 under 35 U.S.C. § 103(a), as being anticipated by Fischell, et al., U.S. Patent 6,272,379, in view of Avitall, et al., U.S. Patent 6,171,237. The Examiner relies on the Fischell, et al. reference for its disclosure of a system for detection of cardiac events which includes a patient alarm means. The Examiner admits that the Fischell, et al. reference does not disclose an escalating alarm, however, the Examiner relies on the Avitall, et al. reference for its disclosure of an audible alarm which increases in volume until a manual reset action is taken. The Examiner then concludes that it would have been obvious to one of ordinary skill in the art to implement the

escalating alarm of Avitall, et al. in the system of Fischell, et al.. The Examiner rejects Claims 10-17, 19-21, 23, and 24-26 under 35 U.S.C. § 103(a), as being unpatentable over Fischell, et al. in view of Avitall, et al., and further in view of Lebel, et al. U.S. Patent 6,571,128. The Examiner relies on the Lebel, et al. reference for its disclosure of an audio alarm that is programmable to emit different frequencies, at different volume levels, for different durations, and with different repetition patterns, used to signal different conditions.

It is respectfully submitted that the Fischell, et al. reference is directed to an implantable electronic system for detecting cardiac events. Responsive to such detection, the system provides output signals to implanted alarm means 48 and external alarm means 71. However, nowhere does the reference disclose or suggest any method for escalating sensory stimulation, and in particular, escalating sensory stimulation be decreasing the intra-set time interval in successive sets of alerting signals during the predetermined time period, or by escalating sensory stimulation by a progressively decreasing inter-set time interval being inserted between successive sets of alerting signals, or the alarm signal escalating in sensory stimulation by the number of alerting signals in each set increasing over time, or the alarm signal escalating in sensory stimulation by the number of alerting signals in each set increasing over time and the time interval between alerting signals in the sets of alerting signals progressively decreasing over time, or the alarm signal escalating in sensory stimulation by the alerting signals

increasing in duration over time, the alarm signal escalating in sensory stimulation by the alerting signals progressively increasing in frequency over time, as now claimed.

The Avitall, et al. reference does not overcome the deficiencies of Fischell, et al. The Avitall, et al. reference is directed to a remote health monitoring system which includes an audible alarm coupled to a volume control, the volume control providing automatic increase in volume of the audible signal until a manual reset action is taken. Thus, while the reference clearly discloses a system wherein the amplitude of the alarm signal is increased progressively in order to escalate sensory stimulation thereof, nowhere does the reference disclose or suggest any system wherein sensory stimulation is escalated by changing of the time period between groups of pulses, the time between pulses within groups, the duration of pulses, the frequency of the pulses, and combinations thereof, as now claimed.

Thus, as neither Fischell, et al. nor Avitall, et al. disclose or suggest the concatenation of elements that form the invention of the subject Patent Application, the combination of Fischell, et al. and Avitall, et al. cannot make obvious the invention of the subject Patent Application, as now claimed. One skilled in the art would only be motivated to progressively increase the amplitude of the alarm in the system of Fischell, et al. based on the teachings of Avitall, et al.

The Lebel, et al. reference does not overcome the deficiencies of Fischell, et al. combined with Avitall, et al. The Lebel, et al. reference is directed to a

microprocessor controlled ambulatory medical apparatus. In particular, the device is utilized in conjunction with an implantable infusion pump and includes both an audio alarm and a vibrator for alerting the patient of various warnings and alarm conditions. The alarms are programmable to emit different frequencies, at different volume levels, for different durations and with different repetition patterns that are "used to signal different conditions", column 27, lines 48-57. Thus, the system utilizes the alternative alarm patterns to differentiate one type of alarm condition or warning from another. However, nowhere does the reference disclose or suggest providing an escalating sensory stimulation by changing those programmable parameters during the course of the alarm condition. As the Avitall, et al. reference provides no motivation for decreasing time periods between repetitive patterns, increasing the duration of pulse signals, increasing frequency, or the number of alerting signals in each set of repeating groups of signals, as is now claimed, it could only be through the impermissible use of "hindsight" that the Examiner suggests such a combination of references and such a result therefrom, using Applicant's own disclosure as a "blueprint" therefore.

Thus, the combination of Fischell, et al., Avitall, et al., and Lebel, et al., cannot make obvious the invention of the subject Patent Application, as now claimed.

In the Official Action, the Examiner rejected Claims 8-9 under 35 U.S.C. § 103(a), as being unpatentable over Ujhelyi, et al., in view of Ferek-Petric, U.S.

Patent 5,076,272. Claims 25, and 28-40 were rejected under 35 U.S.C. § 103(a), as being unpatentable over Ujhelyi, et al., in view of Amano, et al., U.S. Patent 6,095,984.

As discussed above with respect to the Ujhelyi, et al. reference, the Examiner has misinterpreted the disclosure with respect to the "tiered alerts". Rather than being directed to tiered alarm signal sequence, as the Examiner contends, the tiered alerts referred to in the reference are directed only to the criteria utilized to trigger an alarm condition, and not the alarm signals generated by the system in response to the alarm condition.

Therefore, the combination of the Ujhelyi, et al. reference with either of Ferek-Petric or Amano, et al. cannot make obvious the invention of the subject Patent Application, as claimed, neither of Ferek-Petric or Amano, et al. disclose ot suggest alarm signal that provide escalating sensory stimulation.

For all of the foregoing reasons, it is now believed that the subject Patent Application has been placed in condition for allowance, and such action is respectfully requested.

Respectfully submitted,
For: ROSENBERG, KLEIN & LEE

David I. Klein
Registration #33,253
Dated: 1 Feb. 2006

3458 Ellicott Center Drive, Suite 101
Ellicott City, MD 21043
(410) 465-6678
Customer No. 04586